

Appln. No. 10/782,482
Response to Office Action Mailed June 21, 2005

Docket No. 97728.00139

REMARKS

In response to the prior restriction requirement, Applicant elected *Lactobacillus rhamnosus* of claim 3 for examination. Claims 1-16 are pending in this application to the extent that they read on the elected subject matter. In this response, the applicant has amended claims 1-3, 6 and 11-13.

In the Office Action mailed on June 21, 2005, the Examiner has objected to claims 1-3 due to certain informalities. Claims 12 and 15 stand rejected under 35 U.S.C. § 112 for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1-8 and 11-14 stand rejected under 35 U.S.C. § 102(b) as being anticipated by DeJong et al., WO 00/33854. Claims 1-8 and 11-16 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over DeJong. Claims 1-14 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over DeJong in view of Sorkin, U.S. Patent No. 5,952,393. For the reasons set forth below, Applicants respectfully request reconsideration in view of the amendments to the claims and the arguments set forth below.

Claims 1-3 have been amended to correct the informalities noted by the Examiner. Claim 1 has been further amended to recite that the mannanoligosaccharide used in the claimed composition is in one of a purified form, in a bonded or non-bonded complex with proteins, or in a matrix with beta-glucans. Claim 11 has been amended to recite that the composition used in the claimed method contains mannanoligosaccharide in one of a purified form, in a bonded or non-bonded complex with proteins, or in a matrix with beta-glucans. Support for these amendments to claims 1 and 11 may be found in the specification at, for example, page 7, lines 8-11. Claim 6, 12 and 13 have been amended to recite a lower limit of mannanoligosaccharide of 300 mg in the claimed compositions and methods. Claims 12 and 13 have been amended to

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delete the abbreviation "MOS" and replace it with "mannanoligosaccharide". No new matter has been added.

As recited in the claims as amended, the present invention is directed to compositions comprising a probiotic, *Lactobacillus rhamnosus*, and mannanoligosaccharide (MOS). As recited in the amended claims, the compositions may further include fructooligosaccharide (FOS) and formulation aids such as diluents, stabilizers, binders, buffers, lubricants, coating agents, preservatives, emulsifiers and suspension agents. The present invention is also directed to methods of improving GI tract health in humans by administering the composition.

As described in the specification and recited in the amended claims, the MOS used in the compositions and methods of the present invention may be in a concentrated, purified form, in a bonded or non-bonded complex with proteins, or in a matrix with beta-glucans, proteins or other carbohydrates. Page 7, lines 8-11. MOS provides several advantages when used in a composition with a probiotic, such as, for example, *Lactobacillus rhamnosus*. MOS blocks the attachment of pathogens to the host enterocytes and causes the pathogens to be excreted from the GI tract, out of the host body, and hence reduces pathogenic infection of the GI tract. MOS stimulates the production of immunoglobulins (bile IgA, plasma IgG) and the phagocytic activity of macrophages and enhances host immune system defense mechanisms. In addition, MOS promotes the growth of lactic acid bacteria such as *Lactobacillus*, but MOS does not provide a food source for pathogenic bacteria.

DeJong, WO 00/33854, describes formulations containing probiotics and the oligosaccharides TOS (transgalacto-oligosaccharides), fructo-oligosaccharides (FOS) and combinations thereof. Page 2, lines 28-29. In the Office Action, the Examiner has cited a portion of DeJong which describes the inclusion and administration of *Saccharomyces cerevisiae*

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yeast as part of the probiotic composition of DeJong. The Examiner notes that the cell walls of the yeast contain approximately 5.2% MOS. The Examiner then relies on this description to reject the claims of the present application.

As recited in the claims as amended and described in the application, the compositions of the present invention comprise a probiotic and MOS in a purified or combined form. While MOS can be derived from the cell walls of *Saccharomyces cerevisiae*, the compositions and methods of the present invention utilize purified forms of MOS which may be combined with other proteins or carbohydrates, as recited in the claims as amended. Providing MOS through the addition of live or dead *Saccharomyces cerevisiae* cells is not desirable, as the yeast cells must be processed to obtain the MOS rather than having the MOS readily available as in the compositions recited in the amended claims.

Claims 1-8 and 11-14 stand rejected under 35 U.S.C. § 102(b) based upon DeJong. In order to anticipate a claim under section 102(b), each and every element of the claimed invention must be found in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 1349, 1351 (Fed. Cir. 1987); MPEP § 2131. The claims as amended recite a composition, and methods for using the composition, in which MOS is provided in purified form, in a bonded or non-bonded complex with proteins, or in a matrix with beta-glucans, proteins or other carbohydrates. DeJong describes only a combination of a probiotic bacteria and a yeast such as *Saccharomyces cerevisiae* which contains some amount of MOS in the cell walls. DeJong does not describe a composition containing MOS in any of the forms recited in the claims as amended. Accordingly, DeJong does not describe a composition having each and every element recited in the claims as amended, and DeJong therefore does not anticipate claims 1-8 and 11-14 as amended for at least this reason.

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Moreover, claims 6, 12 and 13 have been amended to recite compositions and methods in which the minimum quantity of MOS in the composition is 300 mg. As noted by the examiner, in the compositions described by DeJong, the maximum amount of MOS that is present in the yeast cell walls is approximately 260 mg. Accordingly, the compositions described in DeJong do not anticipate claims 6, 12 and 13 for at least this additional reason.

Claims 1-3 and 11-16 also stand rejected under 35 U.S.C. § 103(a) under DeJong. As to claims 1-6 and 11-13, the examiner merely states as a basis for the rejection that DeJong anticipates the claims under section 102(b). For at least the reasons set forth above, DeJong does not anticipate claims 1-6 and 11-13 as amended. Moreover, DeJong does not teach or suggest a composition comprising probiotics and MOS provided in purified form, in a bonded or non-bonded complex with proteins, or in a matrix with beta-glucans, proteins or other carbohydrates. Accordingly, claims 1-6 and 11-13 are not obvious under section 103 in view of DeJong.

As to claims 7-8 and 14-16, the examiner states that it would have been obvious to one skilled in the art to administer 100 mg to 25 g of fructooligosaccharide based on the disclosure in DeJong to administer *L. rhamnosus* in combination with 2.3 grams of an oligosaccharide such as FOS as described in the example in DeJong regarding a synbiotic bar. Claims 7-8 and 14-16 claim compositions, and methods of using compositions, comprising probiotics, MOS provided in purified form, in a bonded or non-bonded complex with proteins, or in a matrix with beta-glucans, proteins or other carbohydrates, and fructooligosaccharide (FOS). DeJong does not describe, teach or suggest a composition combining these ingredients. In particular, as discussed above, DeJong does not describe, teach or suggest compositions comprising MOS provided in purified form, in a bonded or non-bonded complex with proteins, or in a matrix with beta-

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glucans, proteins or other carbohydrates. Accordingly, for at least this reason, claims 7-8 and 14-16 are not obvious in view of DeJong.

Claims 1-14 also stand rejected under 35 U.S.C. § 103(a) as being unpatentable over DeJong in view of Sorkin, U.S. Patent No. 5,952,393. In this rejection, the examiner states that claims 1-8 and 11-14 are anticipated by DeJong. As discussed above, claims 1-8 and 11-14 as amended are not anticipated by DeJong, and are not obvious in view of DeJong. Sorkin is cited by the examiner merely for the disclosure of the use of various formulation aids in a nutritional supplement composition. Sorkin does not add anything to the description in DeJong regarding the combination of probiotics with MOS provided in purified form, in a bonded or non-bonded complex with proteins, or in a matrix with beta-glucans, proteins or other carbohydrates. Accordingly, claims 1-8 and 11-14 as amended are patentable over DeJong in view of Sorkin.

The examiner has rejected claims 9 and 10 as unpatentable over DeJong in view of Sorkin. As discussed above, DeJong does not describe, teach or suggest the compositions of claims 9 and 10 as amended because DeJong does not describe compositions comprising probiotics in combination with MOS provided in purified form, in a bonded or non-bonded complex with proteins, or in a matrix with beta-glucans, proteins or other carbohydrates. Sorkin merely describes formulation aids, and does not address the deficiency of DeJong. Accordingly, claims 9 and 10 are patentable over DeJong and Sorkin in view of the amendments to the claims.

In view of the foregoing remarks, this application should now be in condition for allowance. A notice to this effect is respectfully requested. If the Examiner believes after considering these remarks, that the application is not in condition for allowance, the Examiner is requested to call the Applicant's attorney at the telephone number listed below.

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Because the reasons above are sufficient to traverse the rejection, Applicants have not explored, nor do they now present, other possible reasons for traversing such rejections. Nonetheless, Applicants expressly reserve the right to do so, if appropriate, in response to any future Office Action.

Applicant has filed herewith a petition for a three month extension of time under 37 C.F.R. § 1.136(a) for filing a response in the above-referenced Office Communication, extending the time for response from September 21, 2005 to December 21, 2005. No additional fee is believed to be required. Should the Commissioner deem additional fees to be due in connection with this application, Applicant's attorney hereby authorizes that such fee be charged to Deposit Account No. 50-3569.

Respectfully submitted,

Date: December 21, 2005_

By: 

Eric Grondahl, Esq.
Attorney for Applicant
Reg. No. 46,741
McCarter & English, LLP
CityPlace I
185 Asylum Street
Hartford, CT 06103
Phone: (860) 275-6704